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VIA CM/ECF
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court for the District of New Jersey

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*
No. 1:19-md-02875-RBK-JS (D.N.J.)

Dear Judge Schneider:

The Retailer and Pharmacy Defendants (collectively the "Retail Pharmacy Defendants") respectfully submit this letter brief addressing the "macro" discovery disputes as raised in Plaintiffs' April 13, 2020 letter brief (ECF 413), per the modified schedule approved by the Court on May 13, 2020 (ECF 432).

I. Introduction

Plaintiffs allege that the Manufacturer Defendants introduced a new solvent into the manufacturing process for generic valsartan, which Plaintiffs claim resulted in NDMA contamination of the finished drug. (*E.g.*, ECF 398 at ¶ 6.) The Retail Pharmacy Defendants are not alleged to have done anything but dispense finished dose prescription drugs manufactured by other Defendants pursuant to valid prescriptions. (*E.g., id.* at ¶¶ 407-410 (warranty allegations against retailers)). Indeed, in their case management proposal, Plaintiffs have even proposed a first trial without the Retail Pharmacy Defendants.[1] (ECF 420 at 4-5.) Although Plaintiffs dispute that the Retail Pharmacy Defendants are "unfairly swept up in this litigation," their only support for this statement is that these Defendants are large corporations with substantial market share. (ECF 413 at 1-2.) In other words, Plaintiffs offer no reason why these defendants are responsible for a prescription drug's alleged latent defect. This is not surprising, given the overwhelming case law holding that pharmacies do not have a duty to test and are not liable for latent defects in a prescription medication. *E.g.*, *Bichler v. Willing*, 58 A.D.2d 331, 333, 397 N.Y.S.2d 57, 58 (1977) ("Nor can plaintiffs recover in negligence on the hypothesis that appellant dispensed the drug without first inspecting or testing it for the purpose of discovering its latent dangers.").

Nonetheless, because the Court had previously indicated that it would not hear Rule 12 motions before discovery began, the Retail Pharmacy Defendants have engaged in extensive meet-

[1] Plaintiffs indicated that they wish to proceed with a class trial against ZHP and its affiliated entities, and potentially finished dose manufacturers, claiming that such a trial "would provide a tremendous amount of information and guidance across the litigation." (ECF 420 at 4-5.) While nothing in this letter should be interpreted as consenting to Plaintiffs' unprecedented approach to consolidated case management or class certification, and the Court has decided to withhold ruling on how any claims would be tried and against which parties until after the forthcoming Rule 12 and class certification motions, the Retail Pharmacy Defendants mention Plaintiffs' request because it highlights that even Plaintiffs do not think the Retail Pharmacy Defendants (and thus discovery from them) are necessary at this time.

and-confer negotiations with Plaintiffs, made substantial concessions during these sessions, and agreed to produce documents to Plaintiffs, including certain consumer-level purchase records and data concerning valsartan dispensed to consumers over a period of nearly a decade.[2] The Retail Pharmacy Defendants anticipate having to begin the burdensome process of collecting and producing these documents in the coming months, while simultaneously raising their Rule 12 defenses, including those demonstrating immunity provided to pharmacies.

Despite the Retail Pharmacy Defendants' agreement to produce such a significant amount of discovery, Plaintiffs seek more, including the production of highly sensitive, proprietary, and confidential pricing information that they claim is relevant to a calculation of retailers' purported "ill-gotten gains." More specifically, Plaintiffs seek the production of (1) upstream cost data (*i.e.* what the retailers paid for valsartan) and (2) downstream pricing data reflecting reimbursements from third-party payors ("TPPs") (*i.e.* what insurers paid to the pharmacies for valsartan). The Retail Pharmacy Defendants have refused to produce this data because, as discussed more fully below, it is irrelevant to the core allegations and theories of liability asserted against the Retail Pharmacy Defendants. Rather, such materials are relevant only to the extent Plaintiffs are able to plead and prove their entitlement to the disgorgement of retailer profits. (ECF 413 at 4 (referencing allegedly "ill-gotten gains").[3] But Plaintiffs have not come close to demonstrating that they may pursue a disgorgement remedy against the Retail Pharmacy Defendants, and any claimed relevance of this data is speculative at best. *See, e.g.*, *Van Orman v. Am. Ins. Co.*, 680 F.2d 301, 310 (3d Cir. 1982) (reversing judgment on unjust enrichment claim). Plaintiffs' requests for the discovery now at issue before the Court are wholly inconsistent with the claims alleged and the role of the Retail Pharmacy Defendants in this litigation.

Moreover, the documents requested are among the most commercially sensitive information in the possession of the Retail Pharmacy Defendants, as shown by the attached declarations. *See* Exhibits A through N (listed in addendum). Because Plaintiffs are not entitled to disgorgement as a remedy against these Defendants, and they have offered no basis for obtaining these most highly confidential, protected, nonpublic and commercially sensitive data, the information they seek is outside the scope of permissible discovery. *See* Fed. R. Civ. P. 26(b)(1) (the scope of discovery must be "relevant to any party's claim or defense and proportional to the

[2] Although the Retail Pharmacy Defendants agreed to produce documents, their production will not allow Plaintiffs to identify and trace the specific batch of valsartan a particular consumer received. Plaintiffs misleadingly and incorrectly claim that the Drug Supply Chain Security Act was intended to "track product from the manufacturer to the consumer." (ECF 413 at 9 at n.9.) That is simply not so. Direct sales to consumers are exempt from the product tracing requirements under the Act. 21 U.S.C. § 360eee(24)(B). Although the Act requires the retail pharmacy to provide transaction information to subsequent owners of prescription drugs, this requirement is not applicable to, among other things, dispensing to a patient. *Id.* In other words, the Act does not require transaction history be provided to patients at the point of sale.

[3] In one sentence, Plaintiffs claim that upstream cost data (what the Retail Pharmacy Defendants paid for valsartan from their suppliers) is "relevant to motive, intent, and notice," citing their prior and unrelated arguments to the Court about manufacturers and the cost of recycled solvents within the manufacturing process. ECF 413 at 4. Plaintiffs make no argument specific to the Retail Pharmacy Defendants, and surely must concede that any purported link between retailer product costs and purported "motive, intent, and notice" (which Plaintiffs do not attempt to identify) would be acutely more attenuated than direct manufacturing-process costs, even before considering the added complexity of the generic drug supply chain and pricing. *See, e.g.*, Declaration of Zachary Mikulak, attached as Exhibit A, at ¶ 6.

needs to the needs of the case" considering many factors, including "the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit."). The information Plaintiffs now request is not relevant to any valid claim against the Retail Pharmacy Defendants, and thus is outside the scope of discovery on that basis alone. But even if it possessed marginal relevance, which the Retail Pharmacy Defendants deny, it is disproportional to the needs of the case as the burden and risk of producing the information far outweighs its negligible benefit. As demonstrated by the submitted declarations, the production of this information will have lasting, harmful effects in the acquisition and sale of prescription pharmaceuticals in the marketplace. The Retail Pharmacy Defendants therefore respectfully request that Plaintiffs' discovery demands be denied.

II. Relevant Procedural History and Remaining "Macro" Issues

Following a discovery conference on November 6, 2019, the Court ordered Plaintiffs to serve initial Rule 34 discovery on the downstream defendants on or before November 26, with the downstream defendants' objections to the requests due three weeks later, on December 17. On the November 26 due date, Plaintiffs served omnibus Distributor/Wholesaler/Pharmacy Requests for Production, comprising 65 individual document requests, with more than 150 discrete subparts, on 15 separate topics, and with responses contemplating substantial custodial and non-custodial document/ESI collection and production. Following an initial meet and confer about the impracticality and scope of the requests, Plaintiffs agreed to serve amended requests upon the Retail Pharmacy Defendants, and to revisit the discovery schedule, including the timing of objections, upon service of the amended discovery.

On December 10, 2019, Plaintiffs served amended requests. Unfortunately, however, the amendments did not address the Retail Pharmacy Defendants' concerns; the amended requests comprised 60 individual document requests, again with more than 150 discrete subparts, on 15 separate topics, and with responses contemplating substantial custodial and non-custodial collection and production. In many instances, the amended requests were broader than the initial requests and imposed greater discovery obligations upon the downstream defendants than on the manufacturers. Thus, in a December 18, 2019 email, the Court struck the entire set of discovery and asked Plaintiffs "to go back to the drawing board, sharpen their pencils and serve a new streamlined set of requests."

With those guideposts in mind, the Retail Pharmacy Defendants engaged in significant meet-and-confer negotiations in the first quarter of 2020. To facilitate discussions, counsel for the Retail Pharmacy Defendants provided Plaintiffs with a set of proposed discovery that, in their view, reflected the Court's guidance regarding the appropriate scope of "core" discovery, and that reflected the categories of information that the Retail Pharmacy Defendants could realistically produce. Plaintiffs responded with a different set of document requests, which the parties were able to work to narrow.

After several subsequent discovery conferences, the Retail Pharmacy Defendants and Plaintiffs agreed in principle on most issues, with the exception of the upstream cost data and TPP reimbursement rates and data. The Retail Pharmacy Defendants agreed to produce, where available (and availability often varies from retail pharmacy to retail pharmacy), centrally stored

documents sufficient to identify, in brief: (1) the valsartan purchased by them from January 1, 2012 through the end of 2019; (2) as exemplar, the ordinary-course transactional documents accompanying valsartan purchased by them; (3) as exemplar, the type of manufacturer-included packaging or labeling information for valsartan dispensed by them; (4) the sale of valsartan to consumers; (5) the price paid by consumers for valsartan; (6) the information provided to them by the Manufacturer or Wholesaler Defendants from which they actually purchased valsartan; and (7) the identity of distribution centers that would have received or shipped valsartan. The Retail Pharmacy Defendants also agreed to produce several categories of documents relating to recalls and final written policies about a number of topics, including those relating to warranties, product tracing, and document retention. The Retail Pharmacy Defendants also agreed to produce in redacted form final written indemnification agreements with any supplier from whom they purchased the valsartan at issue in this litigation.

The only remaining issue for this "core" set of discovery relates to disgorgement of profits. Plaintiffs seek information about what the Retail Pharmacy Defendants paid for valsartan—their upstream cost data. Plaintiffs also seek information about what TPPs reimbursed the Retail Pharmacy Defendants for valsartan—the TPP pricing data.

III. Argument

Plaintiffs' discovery requests for upstream cost (supplier pricing information) and production of data concerning TPP payments to the Retail Pharmacy Defendants should be denied. The discovery at issue relates only to a disgorgement of profits remedy, which is not available to Plaintiffs, and is not proportional to the needs of the litigation, especially in light of the exceptionally sensitive nature of the data requested. Indeed, Plaintiffs' stated intention not to try a case against the Retailer Defendants anytime soon (ECF 420 at 4-5) proves that their demand for the requested documents is not proportional to the current needs of the case.

A. Disgorgement of profits is not an available remedy to Plaintiffs.

Plaintiffs seek gross and net upstream cost data and TPP reimbursement rates to support a "disgorgement of profits" damages theory. But the equitable remedy of disgorgement is not available given Plaintiffs' ample remedies at law, and the Economic Loss Master Complaint fails to plead any circumstances that would make disgorgement appropriate in any event.

Plaintiffs argue that they are entitled to documents showing gross and net upstream cost data and TPP reimbursements because they "plead a variety of claims that permit disgorgement of ill-gotten gains (e.g., unjust enrichment)." (ECF 13 at 4.) (emphasis added). Plaintiffs misrepresent the case they brought. Of the nine causes of action pled against the Retail Pharmacy Defendants in the Consolidated Second Amended Economic Loss Class Action Complaint, Plaintiffs only seek disgorgement of any alleged "ill-gotten gains" as to one—Count 13 for unjust enrichment. *Compare* ECF No. 398 at ¶ 560 (seeking disgorgement), *with id.* at ¶¶ 435-445, 455-465, 475-482, 491-503, 517-529, 543-548, 567-576, 587-594 (the remaining eight claims against the Retail Pharmacy Defendants, none of which seeks disgorgement).

In fact, Plaintiffs' other claims against the Retail Pharmacy Defendants—including multiple warranty claims based on the alleged contract formed between Plaintiffs and the Retail

Pharmacy Defendants at the time of sale—prohibit Plaintiffs from pursuing a claim for unjust enrichment or disgorgement of profits. *See, e.g.*, *id.* at ¶ 437 (alleging contract). Because these other claims provide Plaintiffs with adequate remedies at law, Plaintiffs' claim for equitable relief fails as a matter of law in all eighteen states for which there is a named class representative in the Second Amended Economic Loss Class Action Complaint.[4] Simply put, since Plaintiffs have alleged the existence of a valid contract between themselves and the Retail Pharmacy Defendants, they have pled themselves out of court on their unjust enrichment claim.

Even if Plaintiffs were found to have pled unjust enrichment in the alternative (which they have not), Plaintiffs' request for disgorgement also fails because Plaintiffs do not adequately plead a basis for such relief. As an equitable claim, unjust enrichment is only appropriate in circumstances where it would be "unjust" for the tortfeasor to retain the benefits received. *See Goldsmith v. Camden Cty. Surrogate's Office*, 975 A.2d 459, 462 (N.J. Super. Ct. App. Div. 2009) ("The doctrine of unjust enrichment rests on the equitable principle that a person shall not be allowed to enrich himself unjustly at the expense of another"); *see also Cty. of Essex v. First Union Nat. Bank*, 891 A.2d 600, 605-06 (N.J. 2006). Furthermore, disgorgement of profits is only available where the "conscious wrongdoing" is such that it "tips the scale" in favor of awarding such a unique form of relief. *See* Restatement (Third) of Restitution and Unjust Enrichment § 3 cmt. a ("Liability to disgorge profits is ordinarily limited to cases of … 'conscious wrongdoing,' because the disincentives that are the object of a disgorgement remedy are not required in dealing with … inadvertent tortfeasors.").[5] For example, disgorgement of profits has been found

[4] *See Resnick v. Hyundai Motor Am. Inc.*, 2017 WL 1531192, at *22 (C.D. Cal. Apr. 13, 2017) (noting that, in California, quasi-contractual claims like unjust enrichment cannot lie where there is an express contract as a result of a warranty, and citing cases standing for that proposition under the laws of Florida, Georgia, Louisiana, Massachusetts, North Carolina, South Carolina, and Texas); *Richard Parks Corrosion Tech., Inc. v. Plas-Pak Indus., Inc.*, 2015 WL 5708539, at *4 (D. Conn. Sept. 29, 2015) (under Connecticut law, "[l]ack of a remedy under contract is a precondition for recovery based upon unjust enrichment."); *Blue Frog Movil NV Inc. v. Navicomm LLC*, 2007 WL 3334793, at *2 (S.D. Ind. Nov. 8, 2007) (under Indiana law, "the existence of a contract precludes the pursuit of an equitable remedy" by party to that contract); *Ice Corp. v. Hamilton Sundstrand, Inc.*, 444 F. Supp. 2d 1165, 1170 (D. Kan. 2006) ("Kansas law is clear that … unjust enrichment" is not appropriate "when an enforceable express contract regulates the relations of the parties with respect to the disputed issue."); *Multiplan, Inc. v. Holland*, 2016 WL 3983669, at *3 (S.D. Miss. July 25, 2016) ("unjust enrichment only applies to situations where … there is no legal contract" under Mississippi law); *Van Orman v. Am. Ins. Co.*, 680 F.2d 301, 310 (3d Cir. 1982) ("recovery under unjust enrichment may not be had when a valid, unrescinded contract governs the rights of the parties" under New Jersey law); *Steadfast Ins. Co. v. Legacy Safety & Consulting, LLC*, 2015 WL 12803775, at *4 (D.N.M. June 25, 2015) ("New Mexico law strongly disfavors unjust enrichment claims when remedies exist under contract law."); *Downey v. Adloox Inc.*, 238 F. Supp. 3d 514, 526 (S.D.N.Y. 2017) ("It is one of the well-settled principles of New York law that the existence" of a "contract governing a particular subject matter ordinarily precludes recovery in quasi contract for events arising out of the same subject matter."); *Wuliger v. Mfrs. Life Ins. Co. (USA)*, 567 F.3d 787, 799 (6th Cir. 2009) ("Ohio law is clear that a plaintiff may not recover under the theory of unjust enrichment … when an express contract covers the same subject."); *Sheinman Provisions, Inc. v. Nat'l Deli, LLC*, 2008 WL 2758029, at *4 (E.D. Pa. July 15, 2008) ("Pennsylvania law prohibits unjust enrichment claims where a contract governs the relationship of the parties"); *CGI Fed. Inc. v. FCi Fed., Inc.*, 814 S.E.2d 183, 190 (Va. 2018) (under Virginia law, "t]he existence of an express contract covering the same subject matter of the parties' dispute precludes a claim for unjust enrichment").

[5] It therefore makes sense that the proper remedy for strict liability torts is restitution, not disgorgement. *Compare id.* at § 3 cmt. a, *with id.* at § 51 cmt. a ("Strict liability in tort creates the possibility of actionable wrongdoing without culpability: the unjust enrichment of tortfeasors without fault … is accordingly measured [through restitution]").

appropriate in cases that involve a breach of fiduciary duty, profits derived from the diversion of business that otherwise would have gone to the plaintiff, or securities fraud.[6]

Here, Plaintiffs have not pled any facts that would warrant the Retail Pharmacy Defendants being required to disgorge their profits to Plaintiffs. Indeed, Plaintiffs have not alleged that the Retail Pharmacy Defendants acted in bad faith, that their profits are rightly owed to Plaintiffs because they resulted from the diversion of Plaintiffs' business, or even that Plaintiffs did not receive the therapeutic value of the valsartan medication they paid for, as FDA recommended patients keep taking recalled valsartan until they could obtain a substitute, given its health benefits. *See, e.g.*, *District 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 532-33 (D.N.J. 2011) (holding that "alleged overpayment" could not sustain unjust enrichment claim where drug was not inferior, not inadequate, and did not cause personal injuries).

Further, contrary to Plaintiffs' assertions, pharmacies do not have a duty to test prescriptions for latent defects. *E.g. Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 87 (E.D. Pa. 1986) (rejecting a duty to test on the part of a pharmacist). Indeed, pharmacies are often immune from liability—whether warranty-based or tort-based—for dispensing a prescription with a latent defect. *E.g.*, *In re Rezulin Prod. Liab. Litig.*, 133 F. Supp. 2d 272, 292 (S.D.N.Y. 2001) ("[A]lmost every state that has considered the issue has declined to find pharmacists liable for breach of either implied or express warranty with respect to properties of prescription drugs."). Here, Plaintiffs merely allege that the Retail Pharmacy Defendants dispensed valsartan that, unbeknownst to the Retail Pharmacy Defendants, may have included an impurity created during the manufacturing process for which these Defendants had no obligation to test. *See In re Scotts EZ Seed Litig.*, 304 F.R.D. 397, 413 (S.D.N.Y. 2015) (rejecting "disgorgement of ill-gotten gains" class damages model because it did not match plaintiff's legal theory that the product was worthless and plaintiffs were therefore entitled to their money back). In doing so, Plaintiffs concede—and the law recognizes—that the Retail Pharmacy Defendants are not "conscious wrongdoers," and therefore that disgorgement of profits is not an appropriate remedy.

B. TPPs did not bring suit against the Retail Pharmacy Defendants and Consumer Plaintiffs do not have standing to pursue disgorgement relating to payments made by the TPPs.

The Consumer Plaintiffs seek production of documents showing how much the TPPs paid or reimbursed the pharmacies whenever a plan member purchased valsartan. Plaintiffs claim that production of these highly confidential reimbursement rates is to "establish individual and aggregate damages, . . . especially . . . to calculate Retail Pharmacy Defendants' ill-gotten gains." (ECF 413 at 4.) As discussed above, Plaintiffs are not entitled to disgorgement as a remedy. Even

[6] *See, e.g.*, *Vibra-Tech Engineers, Inc. v. Kavalek*, 849 F. Supp. 2d 462, 497-98 (D.N.J. 2012) (breach of fiduciary duty); *Truck Equipment Service Co. v. Fruehauf Corp.*, 536 F.2d 1210, 1221-23 (8th Cir. 1976) (disgorgement awarded when the defendant used pictures of a competitor's trailer in its ads and copied the trailer's distinctive external design); *S.E.C. v. Hughes Capital Corp.*, 917 F. Supp. 1080, 1085 (D.N.J. 1996) (unlike restitution, disgorgement "does not seek to compensate the victims of the wrongful act," but is meant to "prevent the wrongdoer from enriching himself by his wrongs"). Some states require bad faith for disgorgement of profits. LA Civ. Code Art. 2303 ("A person who in bad faith received a payment or a thing not owed to him is bound to restore it with its fruits and products.") (emphasis added). Plaintiffs have not alleged that the Retail Pharmacy Defendants acted in bad faith, so the Louisiana plaintiff's claim for disgorgement fails under Louisiana law.

so, while the Retail Pharmacy Defendants are named as defendants in the Economic Loss Class Master Complaint, it is only as to the claims asserted by the Consumer Plaintiffs—not the TPP Plaintiffs. (ECF 398, even-numbered counts.) The Consumer Plaintiffs are certainly not entitled to recover damages for what TPPs—themselves plaintiffs—paid for valsartan, when the TPPs have separate claims for those damages and have chosen not to name the Retail Pharmacies as defendants.

Put another way, to the extent the Consumer Plaintiffs have suffered no actual harm (because, for instance, they had no co-pay for valsartan), they have no standing to bring any type of economic loss claim. Without a direct financial loss, they have no injury in the economic loss actions. *See, e.g.*, *Wheeler v. Travelers Ins. Co*., 22 F.3d 534, 538-39 (3d Cir. 1994) (plaintiff did not have standing to pursue claims from automobile insurer's denial of her claim where "Medicare paid the medical expenses for which she seeks a recovery" because she was not herself injured); *Barows v. Chase Manhattan Mortg. Corp*., 465 F. Supp. 2d 347, 367–68 (D.N.J. 2006) (even though plaintiff claimed that the defendants misrepresented the sums they attempted to collect, "the fact that she did not actually pay those fees is fatal to her standing to bring such a claim"); *Finkelman v. Nat'l Football League*, 810 F.3d 187, 195 (3d Cir. 2016) (without out-of-pocket loss, no injury-in-fact to plaintiff).

Here, the Consumer Plaintiffs seek to bootstrap their economic loss damages claims by latching on to alleged damages belonging to the TPPs. Such bootstrapping is not permitted, especially when the TPPs have not sued the Retail Pharmacy Defendants. A Consumer Plaintiff is not entitled to recover a TPP's economic loss; he is only entitled to recover his direct economic loss. For example, if a Consumer Plaintiff pays the same, flat co-payment for any type of prescription drug, branded or generic, he suffers no economic loss associated with purchasing one over the other. *E.g.*, *In re K-Dur Antitrust Litig.*, 2008 WL 2660776, at *11 (D.N.J. Feb. 21, 2008) (consumer who had a flat Medicaid co-pay throughout prospective class damages period suffered no injury; any economic injury was borne exclusively by Medicaid). This is why consumer class actions for economic loss relating to pharmaceutical drug pricing or generic delay invariably exclude consumers "whose out-of-pocket expenditures do not vary with the cost of their prescription drugs"—because those consumers have suffered no economic injury. *E.g.*, *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 347 (E.D. Mich. 2001); *see also, e.g.*, *In re Pharmaceutical Average Wholesale Price Litig.*, 230 F.R.D. 61, 66-67, 69 (D. Mass. 2005) (excluding from class those with flat co-pays and those whose co-pay was reimbursed by an insurer or other third party).

The Consumer Plaintiffs claim to need data on TPP reimbursement rates to use those damages to support their own economic loss claims. But whatever the TPPs reimbursed pharmacies for valsartan—something the TPPs themselves know—that information is an alleged damage belonging to the TPPs, not the end consumers. Discovery into TPP reimbursement rates should be denied.

C. Production of highly confidential upstream cost and TPP reimbursement data is not proportional to the needs of the litigation, particularly now.

Because Plaintiffs are not entitled to a disgorgement remedy and further are not entitled to claim as damages disgorgement relating to TPPs, they have presented no legitimate reason whatsoever for the discovery they seek. Given the significant burden and harm to the Retail Pharmacy Defendants from disclosure of this data, the needs of this litigation simply do not call for production of upstream cost data or TPP reimbursement rates. *See, e.g.*, *Harrington v. Bergen County*, 2017 WL 4387373 (D.N.J. Oct. 3, 2017) (speculative and burdensome discovery request failed proportionality requirements of Rule 26).

The Retail Pharmacy Defendants have submitted 14 declarations demonstrating the significant burden and concomitant harms associated with the production of upstream pricing data and TPP reimbursement rates. The harms associated with revealing this type of data are extreme, and these Defendants vigilantly protect this information at all levels of their respective organizations. *E.g.*, Declaration of John Holderman, Ex. B, at ¶ 10; Declaration of Grace Allen, Ex. C, at ¶ 11; Declaration of Danny Tsai, Ex. D, at ¶ 12.

The Retail Pharmacy Defendants compete with each other, both to obtain generic drugs at the lowest possible cost and to receive reimbursement from TPPs for those drugs at the highest possible rate. Beyond competition among the retailers, numerous suppliers—drug manufacturers, wholesalers, and distributors—are defendants in this litigation. If a drug supplier learned what retailers paid other suppliers for a drug, that supplier could use that information to achieve a lower sticker price. Likewise, significant competitive harm would result if TPP reimbursement rates were disclosed. The production of this data has the potential to cause the Retail Pharmacy Defendants irreparable injury and to upend the entire structure of the generic drug business model. It would adversely affect the cost of generic pharmaceuticals, making them more expensive to individual consumers, including the Plaintiffs themselves.[7] A sample of the declarations shows how imperative it is for the requested information to remain secret:

- "The critical nature of this secrecy cannot be overstated. Indeed, the very integrity of the generic pricing market requires that pricing information be absolutely protected and walled off from other market entities—including the manufacturers, wholesalers, or pharmacies that are defendants in this case—to maximize competitive balance between the various players in this environment, and to ensure access of generic drugs to consumers who require them." Declaration of Matt Perlberg, Ex. E, at ¶ 9.

[7] Beyond the attached declarations, commentators also have argued that disclosure of the sensitive financial data requested here would lead to higher prescription drug prices for the public. *E.g.*, J. Shepherd, *Is more information always better?*, 99 Cornell L. Rev. Online 1, 19 (2013) ("[T]he disclosure of sensitive financial information will undercut the most efficient pharmacy network contracts, leading to higher prescription drug prices."); Federal Trade Commission, April 17, 2007 Letter, https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.nelie-pou-concerning-new-jersey.b.310-regulate-contractual-relationships-between-pharmacy-benefit-managers-and-health-benefit-plans/v060019.pdf, at 10-12 (explaining why mandated disclosure of certain pricing information within the pharmacy supply chain may raise drug prices).

- "The viability of [defendant's] generic drug business therefore demands that the confidentiality of pricing information be fully protected and carefully maintained because of the significant competitive and economic impact if a [defendant] competitor or wholesaler learned what it was paying for a particular drug at a particular time in the drug supply marketplace." Declaration of Dick Derks, Ex. F, at ¶ 8.

- "If PBMs had access to these costs they could effectively lower our reimbursement decreasing our ability to generate margin on the vast majority of our business. Exposing the pricing could also eliminate our ability to negotiate with pharmaceutical manufacturers and wholesalers as they would be able to offer less competitive bids." Declaration of Owen P. McMahon, Ex. G, at ¶ 8.

- Disclosure "would alter the competitive balance that allows the generic drug market to function efficiently. It could also limit [defendant's] ability to negotiate future sales and sourcing contracts." Declaration of Britt Turner, Ex. H, at ¶ 11.

- "If [the requested] information ended up in the hands of a competitor or of suppliers/wholesalers generally, it would be impossible to undo the damage to [defendant's] ability to obtain the most favorable pricing of generic drugs and to pass these costs savings on to [its] customers." Declaration of Zachary Mikulak, Ex. A, at ¶ 11.

In addition, generic drug pricing and reimbursement is often negotiated in the aggregate, rather than on a drug-by-drug basis. *See* Declaration of Erin K. McCoy, Ex. I, at ¶ 7; Declaration of Megan Mistarz, Ex. J, at ¶ 5. Thus, "[c]apturing meaningful drug transaction-level data would be extremely burdensome over any period of time and also would be very difficult, if not impossible, to interpret on a per prescription basis." Declaration of Michael Viirre, Ex. K, at ¶ 9. Therefore, Plaintiffs' request for the gross and net price paid by TPPs for all valsartan dispensed by the Retail Pharmacy Defendants not only is irrelevant and involves incredibly sensitive information, it may also be impossible as a practical matter to be produced as Plaintiffs request.

A confidentiality provision in a protective order is inadequate to address this concern. Although the protective order in this case (ECF 139) restricts disclosure of "restricted confidential information" only to the Court (filed under seal) and the parties' external counsel (ECF 139 at 7, 19), Plaintiffs' explicit purpose in requesting the information is to use it to establish a damages model of disgorgement, which would require disclosure to experts and use in depositions. Regardless of confidentiality protections, individuals outside the Retailer Pharmacy Defendants will have newfound access to the upstream cost and downstream TPP reimbursement documents, which is simply too great a risk for the Retail Pharmacy Defendants to bear. *See, e.g.*, Declaration of Tony Braun, Ex. L, at ¶ 13.

Confidentiality concerns—particularly regarding the sensitive pricing information here—provide a basis for denying discovery when relevancy is low. *E.g.*, *Lakeview Pharmacy of Racine, Inc. v. Catamaran Corp.*, 2017 WL 4310221 (M.D. Pa. Sept. 28, 2017) (quashing subpoena for relevant documents because of the confidentiality within them: "Courts have routinely found that a protective order is insufficient protection against unnecessary disclosure of confidential

information to the requesting party."); *N.M. Oncology & Hematology Consultants, Ltd. v. Presbyterian Healthcare Servs.*, 2015 WL 13650055 (D.N.M. Nov. 23, 2015) ("While the Protective Order reduces the risk of an unprotected disclosure, it certainly does not eliminate it. Given the severe and irreversible economic damages which would occur if improper disclosure occurred, the Court considers the harm of disclosure relatively high.").

Here, the harm of disclosing this confidential financial information towers over any alleged benefit of its production. There is no benefit to producing information about profits period, but that is particularly true now. As noted above, Plaintiffs represented to the Court that their requested first trial would not involve downstream defendants. (ECF 420 at 4-5.) Further, the Court has allowed Defendants to brief Rule 12 motions, which will include separate Retail Pharmacy Defendant-specific arguments, including the innocent seller defense, which will address in greater detail and foreclose any argument regarding the so-called "ill-gotten gains" underlying Plaintiffs' requests here. (ECF 432.) While the parties are briefing Rule 12 motions, the Retail Pharmacy Defendants have agreed to begin producing documents requested by Plaintiffs, outside of the upstream cost data and downstream reimbursement rates at issue here. There simply is no need for the Court to order production of these highly confidential documents at this time, and without the benefit of considering these Defendants' full defenses in their Rule 12 briefing.

IV. Conclusion

In light of the Retail Pharmacy Defendants' role in this case and the very real risks associated with disclosure of the pricing information at issue, the Retail Pharmacy Defendants appreciate the Court's attention to these matters, and to the full understanding of the business model Plaintiffs seek to upend for this entire group of defendants, particularly on such a flimsy proffer of necessity. We therefore request that the Court deny Plaintiffs' requests in full.

Respectfully submitted,

Sarah E. Johnston

Addendum: List of Exhibits

Exhibit A – Declaration of Zachary Mikulak (Walgreens Boots Alliance, Inc.)

Exhibit B – Declaration of John Holderman (CVS Pharmacy, Inc.)

Exhibit C – Declaration of Grace Allen (Express Scripts, Inc.)

Exhibit D – Declaration of Danny Tsai (Humana Pharmacy, Inc.)

Exhibit E – Declaration of Matt Perlberg (Express Scripts, Inc.)

Exhibit F – Declaration of Dick Derks (Walmart Inc.)

Exhibit G – Declaration of Owen P. McMahon (Rite Aid)

Exhibit H – Declaration of Britt Turner (The Kroger Co.)

Exhibit I – Declaration of Erin K. McCoy (CVS Pharmacy, Inc.)

Exhibit J – Declaration of Megan Mistarz (Walgreens Boots Alliance, Inc.)

Exhibit K – Declaration of Michael Viirre (Walmart Inc.)

Exhibit L – Declaration of Tony Braun (Humana, Inc.)

Exhibit M – Declaration of Britt Turner (The Kroger Co.)

Exhibit N – Declaration of Alison Farrell (Rite Aid)